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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,960	10/14/2003	Patrick V. Marasco JR.	Marasco-5	9941
7590 10/19/2005			EXAMINER	
D. N. HALGREN 35 Central St Manchester, MA 01944			HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/684,960	MARASCO, PATRICK V.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 14-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

During a telephone conversation with Donald Halgren on October 12, 2005, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

Acknowledgment is made of applicant's claim for priority as a continuation-in-part under U.S. Patent No. 6,635,035, filed on July 21, 2000.

Claim Objections

Claim 12 is objected to because of the following informalities: there is insufficient antecedent basis for "said first sheet of flexible material". While there is sufficient antecedent basis for the first sheet itself, there is no mention of a first sheet of flexible material in Claim 12 or Claim 1 from which Claim 12 depends. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6-8 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Polyakov et al (U.S. Patent No. 5,437,602).

With respect to **Claim 1**: Polyakov teaches a therapeutic limb treatment bag 20 that is applied to a patient's leg. Bag 20 is folded around a portion of a patient's thigh therefore having a first and second open end. (Figs. 6,11) (Col. 3, lines 45-49) Polyakov teaches supply port 24 and discharge ports 25,26 connected to supply and discharge hoses. (Col. 4, lines 3-6) Polyakov teaches that said discharge ports 25,26 are connected to an outlet valve functioning to control pressure within the bag. (Col. 4, lines 17,18) Examiner is concluding that said valves are located at an inner end so as Polyakov teaches they are accessible to allow pressure control in the inner chamber of bag 20.

With respect to **Claim 2**: As stated with respect to Claim 1, Polyakov teaches that discharge ports 25, 26 are connected to supply and discharge hoses, which have first and second ends by the nature of their structure, and that said discharge ports are connected to outlet valves, which are concluded herein to be one-way valves.

With respect to **Claim 4**: As stated with respect to Claim 1, bag 20 has two open ends when applied and secured to a patient's leg.

With respect to **Claim 6**: Polyakov teaches a structure of bag 50 (Fig. 11) having a frustoconical open end section 50a if inflated and that this section is capable of being sized for different thigh diameters by trimming the outer end 50b of section 50a. (Col. 4, lines 62-67)

With respect to **Claim 7**: As can best be seen from any of Figs. 5,6,9 or 11, said discharge ports 25,26 are both situated at a longitudinal mid-point of bag 20.

With respect to **Claim 8**: Polyakov teaches rim 20a whereupon surgical tape 40 is placed to secure bag 20 to a patient's thigh. (Fig. 7) (Col. 4, lines 45-51).

With respect to **Claim 11**: Polyakov teaches inner layer 51 of bag 50 facing the skin surface that is comprised of a panel 63 of textured "taffeta" PVC fabric, as are apron sections 53-53'. (Col. 5, lines 8-11)

With respect to **Claims 12 and 13**: Polyakov teaches that bag 50 is comprised of blank 51 welded to manifold blank 60 that is centered on the reverse face of blank 51 from ports 56-58, defining an intake manifold space between blanks 51 and 60. (Fig. 10) (Col. 4, lines 43-45, 51,52) It is concluded herein by Examiner based on Figure 10 and the fact that manifold blank 60 can fit entirely within blank 51 when centered that the area of manifold blank 60 is less than that of blank 51.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polyakov ('602) in view of Chandler et al (U.S. Patent No. 5,830,180).

With respect to **Claims 3 and 9**: Polyakov does not teach a waste collection chamber. Chandler teaches a fluid management system for arthroscopic surgery comprising a self-contained waste collection system comprising a plurality of waste containment canisters 73 and 80 connected to body cavity 52 via patient outflow line 68. (Fig. 1) (Col. 7, lines 25-28) Chandler teaches that this design is self-contained and portable, therefore it would be obvious to someone of ordinary skill in the art to connect a collection chamber to the hoses connected to the discharge ports taught by Polyakov as taught by Chandler to hygienically store waste material collected from a wound.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polyakov ('602) in view of Orange et al (U.S. Patent No. 5,817,038).

With respect to **Claim 5**: Polyakov does not teach a means for tightening the second open end opposite rim 20a. Orange teaches a waterproof covering and support for limbs that is comprised of two elastic sealing bands 92,93 located at each end respectively of said covering. It would be obvious to someone of ordinary skill in the art to modify the bag 50 taught by Polyakov to have tightening means at both open ends as taught by Orange as this prevents water from entering during bathing or showering.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polyakov ('602) in view of Greco (U.S. Patent No. 5,312,385).

With respect to **Claim 10**: Polyakov does not teach a support frame for bag 50. Greco teaches a pulsed irrigation chamber for treatment of a patient's limb. Polyakov teaches that frames are well-known in the art (Col. 1, lines 41,42) but bag 50 does not operate in connection with a support frame or has a support frame integral to it. Therefore Greco's support frame is considered herein to be an alternate method of protecting a wound from contamination by touching the surface of a chamber or other enclosure intended for treatment. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'T. Zalukaeva', written over the printed name and title.